

**K252745 Halo Sterile Single-use Radial Fiber (Halo-R-0.40-2.5/Halo-R-0.60-2.5/Novo-R-0.60-1.8/Novo-R-0.40-1.8)**Dec 12, 2025  
105 days to decisionK252745 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k252745/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Aug 29, 2025
Decision date	Dec 12, 2025
Days to decision	105 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Micro-Energy Medical Technology Co., Ltd.</b>
Location	Shenzhen, CN
Contact	Danning Zhu
510(k) history	2 submissions · 2 cleared · 2025-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k252745/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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